K100838

Appendix 2: 510(k) Summary

A. Sponsor

Digirad Corporation
13950 Stowe Drive
Poway, California 92064
Contact Person: Joel Tuckey
Tel: (858) 726-1527
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APR 23 2010

B. Date Prepared: March 23, 2010

C. Device Name

Trade Name:	ergo Imaging System
Common Name:	Camera, Scintillation (Gamma)
Classification Name:	Scintillation (gamma) camera
Device Class:	21CFR 892.1100, Class I
Product Code:	IYX

D. Cleared/Predicate Devices

The ergo Imaging System is substantially equivalent to the following cleared devices:

(1) Notebook Imager (Gamma Camera), cleared on May 28, 1997, under K9641104, and

(2) 2020tc SPECT Imaging System and the SPECTour Chair (SPECT Imaging System), cleared on November 9, 1998 under K982855, and

(3) Cardius-1, Cardius-2, Cardius-3, 2020tc SPECT Imaging System, cleared on July 13, 2005 under K051549, and

(4) Cardius XPO series and 2020tc SPECT Imaging Systems cleared on March 23, 2007 under K070542.

E. Device Description

The proposed changes involve modifications to the 2020tc Imaging System to increase size of the detector head field of view (FOV) from 8"x 8" to 12"x 15". Modifications include mechanical and electrical design changes to support the large field-of-view (LFOV) detector head. The modified device (ergo Imaging System) incorporates Digirad's solid-state RIM detector design, modified with 3mm size pixels required for general purpose planar imaging. The 2020tc Imager detectors currently utilize the same 3mm pixel size.

The detectors used in the modified and predicate device utilize a pixelated, multi-crystal CsI scintillator detector with each pixel optically coupled to a low noise photodiode array. The charge detected from each gamma ray is amplified and processed using an amplifier circuit. The RIM detector design technology is currently used in the Digirad Cardius XPO imager systems with a 6mm pixel size for Cardiac SPECT imaging. The RIM detector has been modified to incorporate a 3mm size pixel required for general planar imaging. The RIM detector design includes electrical and mechanical configurations allowing for field

replacement of detector modules and improved system performance (better energy resolution). The updated design of the RIM detector head assembly allows some of the current sub-systems to be moved into the detector head assembly (air dryer) and simplification of others (cooling and power distribution systems).

The modified device uses the 2020tc Imaging System SeeQuanta Acquisition software, with minor modifications required for use with the 3mm pixel size RIM detector modules.

The 2020tc Imager was initially marketed as the Digirad Notebook Imager (K961104), then re-branded as the 2020tc Imaging System (K982855) when it was used in conjunction with the SPECTour Rotating Chair to obtain SPECT images in patients who are seated in an upright position. The modified device (ergo Imaging System) is a general purpose Nuclear Medicine Imaging device used for planar imaging, the same as the Notebook Imager/2020tc Imager when imaging without the rotating chair.

F. Intended Use

The ergo imaging system is intended to image the distribution of radionuclides in the body by means of a photon radiation detector. In so doing, the system produces images depicting the anatomical distribution of radioisotopes within the human body for interpretation by authorized medical personnel.

The ergo imaging system will be used by trained medical personnel to perform nuclear medicine studies.

G. Technology

The ergo Imaging System utilizes Digirad's solid state detector technology used on other Digirad imaging systems. The LFOV (12" x 15") detector head assembly facilitates being able to image larger areas of the patient with a single acquisition. The changes do not alter the fundamental scientific technology of the predicate device.

H. Testing

Verification and Validation tests were conducted to demonstrate the ergo imaging system functioned as per its specifications. All tests passed with the actual results substantially matching the expected results. The testing shows the system meets the design specifications, which are similar to the predicate device functional specifications. Digirad internal testing and phantom images obtained with the ergo imaging system have demonstrated equivalent efficacy to the predicate devices, and did not raise new questions regarding safety and effectiveness.

I. Conclusion

Testing results demonstrate that the ergo Imaging System meets the specifications and is substantially equivalent to the predicate devices, based on comparisons of intended use and technology, and overall system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 21 2010

Mr. Joel Tuckey
Vice President QA/RA
Digirad Corporation
13950 Stowe Drive
POWAY CA 92064

Re: K100838
Trade/Device Name: ergo Imaging System
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) Camera
Regulatory Class: II
Product Code: IYX
Dated: March 23, 2010
Received: March 24, 2010

Dear Mr. Tuckey:

This letter corrects our substantially equivalent letter of April 23, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

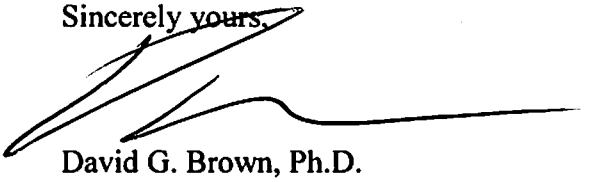
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K100838

Device Name: ergo Imaging System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100838